AMENDED IN ASSEMBLY JUNE 20, 2006

AMENDED IN SENATE MAY 26, 2006

AMENDED IN SENATE APRIL 26, 2006

AMENDED IN SENATE APRIL 6, 2006

SENATE BILL No. 1260

Introduced by Senators Ortiz and Runner

February 9, 2006

An act to amend Sections 125118, 125119, 125119.3, and 125119.5 of, and to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1260, as amended, Ortiz. Reproductive health and research.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 2, 2004, general election (Proposition 71), establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in, the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute, including, but not limited to, establishing standards applicable to research funded by the institute.

Existing law prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses.

Existing law, which is not applicable to research funded under Proposition 71, and which would be repealed on January 1, 2007, requires the State Department of Health Services to, among other things, develop guidelines for research involving the derivation or use of embryonic stem cells, and to report annually to the Legislature.

This bill would delete the repeal date of those provisions, thus indefinitely extending their duration. The bill would also revise the department's reporting duties, by requiring biennial rather than annual reports to the Legislature.

Existing law requires research projects involving the derivation or use of human embryonic stem cells to be reviewed and approved by an institutional review board established in accordance with federal regulations.

This bill would require these research projects to instead be reviewed and approved by a stem cell research oversight committee established substantially in accordance with specified guidelines.

Existing law applicable to fertility treatment requires that a physician and surgeon provide a patient with prescribed information and obtain the patient's informed consent prior to providing the fertility treatment.

This bill, with certain exceptions, would require a physician and surgeon, prior to conducting assisted oocyte production, as defined, or other method of ovarian retrieval for purposes of retrieving eggs for research or for developing medical therapies, to provide the subject with a standardized written summary of health and consumer issues and to obtain the subject's written and oral informed consent for the procedure.

Existing law prohibits a person from knowingly, for valuable consideration, purchasing or selling embryonic or cadaveric fetal tissue for research purposes.

This bill would prohibit human oocytes or embryos from being acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and would prohibit payment in excess of the amount of reimbursement of expenses to be made to any research

subject to encourage her to produce human oocytes for the purposes of medical research.

The bill would declare that it is not to be construed to amend Proposition 71, and would encourage the ICOC to take prescribed actions, including, but not limited to, reviewing studies concerning the health risks and benefits of ovarian stimulation drugs, and undertaking further research.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The purpose of this act is to create protections for research subjects and it should not be construed to affect any other form of medical care.

(b) Scientific research can be most effectively achieved by establishing protocols to protect, respect, and promote human health, safety, dignity, autonomy, and rights in conducting research.

(c) This act seeks to support the requirements already in current law upholding the principle of voluntary and informed consent and to tailor them to this new area of pioneering research that utilizes human oocytes.

(d) The potential for exploitation of the reproductive capabilities of women for commercial gain raises health and ethical concerns that justify the prohibition of payment for human oocytes.

SEC. 2. Section 125118 of the Health and Safety Code is amended to read:

125118. (a) The ~~department~~ *Maternal, Child, and Adolescent Health Branch of the State Department of Health Services* shall develop guidelines for research involving the derivation or use of human embryonic stem cells in California.

(b) In developing the guidelines specified in subdivision (a), the ~~department~~ *branch* may consider other applicable guidelines developed or in use in the United States and in other countries, including, but not limited to, the Guidelines for Research Using Human Pluripotent Stem Cells developed by the National

Institutes of Health and published in August 2000, and corrected in November 2000, and the Guidelines for Human Embryonic Stem Cell Research issued by the National Research Council and Institute of Medicine of the National Academies in 2005.

SEC. 3. Section 125119 of the Health and Safety Code is amended to read:

125119. (a) (1) All research projects involving the derivation or use of human embryonic stem cells shall be ~~reviewed and approved by an institutional review board that is established in accordance with federal regulations, including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations, prior to being undertaken. Any such institutional review board shall, in~~ *reviewed and approved by a stem cell research oversight committee prior to being undertaken. Any stem cell research oversight committee shall, in* its review of human embryonic stem cell research projects, consider and apply the guidelines developed by the department pursuant to Section 125118. ~~An institutional review board~~ *A stem cell research oversight committee* may require modifications to the plan or design of a proposed human embryonic stem cell research project as a condition of approving the research project.

~~(2) For purposes of this article, "IRB" means an institutional review board described in paragraph (1).~~

(2) A stem cell research oversight committee for purposes of this article shall be established substantially in accordance with Guidelines for Human Embryonic Stem Cell Research issued by the National Research Council and the Institute of Medicine of the National Academies in 2005.

(b) Not less than once per year, ~~an IRB~~ *a stem cell research oversight committee* shall conduct continuing review of human embryonic stem cell research projects reviewed and approved under this section in order to ensure that the research continues to meet the standards for ~~IRB~~ *stem cell research oversight committee* approval. Pursuant to its review in accordance with this subdivision, ~~an IRB~~ *a stem cell research oversight committee* may revoke its prior approval of research under this section and require modifications to the plan or design of a continuing research project before permitting the research to continue.

(c) A stem cell research oversight committee may provide scientific and ethical review of research consistent with this article.

SEC. 4. Section 125119.3 of the Health and Safety Code is amended to read:

125119.3. (a) Each ~~IRB~~ *stem cell research oversight committee* that has reviewed human embryonic stem cell research pursuant to Section 125119 shall report to the department, annually, on the number of human embryonic stem cell research projects that the ~~IRB~~ *stem cell research oversight committee* has reviewed, and the status and disposition of each of those projects, *including the information collected pursuant to Section 125342*.

(b) Each ~~IRB~~ *stem cell research oversight committee* shall also report to the department regarding unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance with the requirements or determinations of the ~~IRB~~ *stem cell research oversight committee* with respect to the review of human embryonic stem cell research projects, and the actions taken by the ~~IRB~~ *stem cell research oversight committee* to respond to these situations.

SEC. 5. Section 125119.5 of the Health and Safety Code is amended to read:

125119.5. (a) The department shall at least annually review ~~reports from IRBs pursuant to Section 125120, and may revise~~ *reports from stem cell research oversight committees, and may revise* the guidelines developed pursuant to Section 125118, as it deems necessary.

(b) The department shall report biennially to the Legislature on human embryonic stem cell research activity. These biennial reports shall be compiled from the reports ~~from IRBs pursuant to Section 125120.~~ *from stem cell research oversight committees.*

SEC. 6. Chapter 2 (commencing with Section 125330) is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:

Chapter 2. Procuring of Oocytes for Research

125330. The following definitions shall apply to this chapter:

(a) "Assisted oocyte production" or "AOP" means surgical extraction of oocytes following pharmaceutically induced

manipulation of oocyte production through the use of ovarian stimulation.

(b) "Oocyte" means a female egg or egg cell of a human female.

(c) "Subject" means any person undergoing AOP or any alternative method of ovarian retrieval for research or for the development of medical therapies, including those who would not meet the definition of "subject" under 45 C.F.R. 46.102.

(d) "Alternate method of oocyte retrieval" means a method of oocyte retrieval that does not involve the pharmaceutically induced manipulation of oocyte production.

(e) "Institutional review board" means a body established in accordance with federal regulations, including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations.

125335. (a) Prior to conducting AOP or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval. The failure to provide to a subject this standardized medically accurate written summary constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) The summary shall include, but not be limited to, medically accurate disclosures concerning the potential risks of AOP or any alternative method of oocyte retrieval, including the risks associated with the surgical procedure and with using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP process or any alternative method of oocyte retrieval.

(c) For purposes of subdivision (a), "written summary of health and consumer issues" means the guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients" or an alternative written medically accurate document prepared by a recognized authority on oocyte retrieval for medical research that also meets the criteria included in this

section. This alternative document may be one that has been approved and recommended by the State Department of Health Services pursuant to Section 125118 and shall include all of the following:

(1) The document shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications. The document shall be written in layperson's language and shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the document shall be conveyed to the subject orally in easy to understand and nontechnical terms.

(2) The document shall include additional resources for, or list additional sources of, medical information on health and safety issues surrounding oocyte retrieval.

125340. (a) Prior to providing AOP or any alternative method of ovarian retrieval to a subject for the purposes of medical research or development of medical therapies, a physician and surgeon shall obtain written and oral informed consent for the procedure from the subject. Informed consent for the purposes of this chapter shall comply with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

(b) The failure to obtain written informed consent from the subject constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code. Nothing in this section shall be construed to relieve the physician and surgeon from other existing duties under the law, including, but not limited to, the duty to obtain a subject's informed consent after fully explaining the proposed procedure. The requirement that a physician and surgeon provide the standardized written summary pursuant to Section 125335 is in addition to, and does not supplant, other existing legal requirements regarding informed consent, including, but not limited to, compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20.

(c) This ~~section~~ *chapter* shall not affect the suitability or availability of oocytes procured for research before January 1,

~~2006~~ *2007*, if the oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.

(d) Any written document required pursuant to this section shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications, and in layperson's language. The document shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the written informed consent document shall also be conveyed to the subject orally in easy to understand and nontechnical terms.

125341. An institutional review board (IRB) that reviews and approves medical and scientific research shall require all of the following of any research program or project that comes under its review that involves AOP or any alternative method of oocyte retrieval:

(a) That it include a written summary as required under Section 125335 that would include information on health risks and potential adverse consequences of the procedure and describe the manner in which the subject will receive and review this written summary.

(b) That it obtain informed consent in compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20), *including informed consent for information obtained pursuant to Section 125342*.

(c) That it provide the subject with an objective and accurate statement about the existing state of the research for which the subject is providing oocytes.

(d) That it perform psychological and physical screening, *in accordance with the appropriate standard of care*, for all subjects prior to the oocyte retrieval~~ procedure, following generally recognized standards for the subject's health and safety.~~ *procedure.*

(e) That it ensure that after conducting AOP or any alternative method of oocyte retrieval on a subject, the subject be given a postprocedure medical examination at a time within the standard of care to determine if the subject has experienced an adverse health effect that is a result of the procedure. The subject shall be

informed that she has the right to a second opinion if she has any medical concerns.

(f) That it ensure that the subject has access to and coverage ~~for medical care for any adverse consequence that is a direct~~ *for medically appropriate medical care that is required as a direct* result of the procedure. The research program or project shall ensure that payment or coverage of resulting medical expenses be provided ~~by the program or project~~ *at no cost to the subject* and that a summary of the arrangements the procuring entity has made for coverage or payment for medical care related to AOP or any alternative method of oocyte retrieval is provided to the subject prior to the procedure.

(g) That it provide a summary informing the subject that oocytes may not be sold or transferred for valuable consideration except as set forth in Section 125350.

(h) That it provide disclosure if the physician and surgeon and his or her immediate family members have any professional interest in the outcome of the research or of the oocyte retrieval procedure and, if so, that it provide disclosure that he or she carries the interest of both the subject and the success of the research.

~~(i) That it establish and maintain a written record to include,~~

125342. (a) A research program or project that involves AOP or any alternative method of oocyte retrieval for research purposes shall ensure that a written record is established and maintained to include, but not be limited to, all of the following ~~components, which information shall be made publicly available, on at least a biennial basis:~~ *components:*

(1) The demographics of subjects, including, but not limited to, their age, race, primary language, ethnicity, income bracket, ~~and~~ *education level, and the first three digits of the* ZIP Code of current residence.

(2) Information ~~for every oocyte, sperm, gamete, somatic cell, embryo donation, or product of somatic cell nuclear transfer that~~ *of every oocyte that* has been donated~~, created,~~ or used. This record should be sufficient to determine the provenance and disposition of those materials.

(3) A record of all adverse health outcomes, including, but not limited to, incidences and degrees of severity, resulting from the AOP or any alternative method of oocyte retrieval.

~~(j)~~

(b) The information included in the written record pursuant to subdivision ~~(i) shall not disclose individual~~ *(a) shall not disclose personally identifiable* information about subjects, and shall be confidential and is deemed protected by subject privacy provisions of law. *This information shall be reported to the Maternal, Child, and Adolescent Health Branch of the State Department of Health Services, which shall aggregate the data and make it publicly available in a manner that does not reveal personally identifiable information about the subjects.*

~~125343. Any employee or relative of an employee of a research organization or body is~~

125343. Any employee who works in the unit conducting stem cell research using human oocytes, persons who report to, or are supervised by, the principal investigator or key personnel of the project, or both, along with the principal investigator and the key personnel of the project, and the immediate family members of any of the above persons are prohibited from being a subject in the research.

125344. The physician and surgeon performing the AOP or any alternative method of oocyte retrieval shall not have a financial interest in the outcome of the research.

125345. Pursuant to guidelines adopted by the Research Council and Institute of Medicine of the National Academies, researchers shall offer subjects an opportunity to document their preferences regarding future uses of their donated materials. The consent process shall fully explore whether donors have objections to any specific forms of research to ensure that their wishes are honored.

125346. Any procedures for procuring oocytes in this state for research or the development of medical therapies shall meet all of the standards for subjects included in this chapter. All ~~eggs~~ *oocytes* procured outside of this state for research taking place in this state shall meet these same standards. All egg extractions for research shall be approved by an institutional review board pursuant to Section 125341.

125350. No human oocyte or embryo shall be acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for the purposes of medical research or development of medical therapies. For purposes of this section,

"valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, and storage of oocytes or embryos.

125355. No payment in excess of the amount of reimbursement of direct~~, out-of-pocket expenses~~ *expenses incurred as a result of the procedure* shall be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.~~ There shall be no reimbursement for lost wages.~~

SEC. 7. (a) This act shall not be construed to amend Proposition 71, approved by the voters at the November 2, 2004, general election.

(b) The Independent Citizen's Oversight Committee (ICOC) established pursuant to Section 125290.15 of the Health and Safety Code is encouraged to review existing studies concerning the health risks and benefits of ovarian stimulation drugs used for assisted oocyte production, identify gaps in existing knowledge concerning health risks and benefits, and undertake further research as the ICOC deems necessary to characterize the risks and benefits of those drugs.

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